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PAT data management to enable advanced process monitoring and control on hot melt extrusion lines

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ABSTRACT

Hot melt extrusion (HME) is one of the booming manufacturing techniques in the pharmaceutical industry. Although the technique is not new, it has recently a growing impact on the pharmaceutical production. The extruder is usually combined with different types of downstream equipment to obtain HME-based manufacturing lines capable of manufacturing a variety of solid dosage forms such as pellets and tablets.

PAT is one of the key elements to optimize the monitoring and the control of these HME lines. By adding advanced analyzers into the process (like Near Infrared or Raman), Critical Process Parameters, and Critical to Quality Attributes can be followed in real time. In this discussion, we will present concepts that have been implemented in SIPAT projects in the last years. We are discussing time alignment and data aggregation strategies for HME lines; we will discuss modeling strategies as applied on the data and discuss how these results can be applied in controlling the line. Focus here will be two-fold: we will show how trend charts can be built up with automated statistical data evaluation that can be used to trigger actions, like activating diverters or calculating new set points. In addition, we will show also how closed loop control can be applied on HME lines based on multivariate data.